

Application No. 1010/629,368
Amendment dated August 29, 2006
Reply to Office Action of May 31, 2006

Atty Dkt No. 02-479-C

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REMARKS/ARGUMENTS

In the Office Action the Examiner rejected

(a) claims 1-15, 17-24, and 30 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention;

(b) claims 5 and 25 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

(c) claims 1-30 (provisionally rejected) under the judicially created doctrine of obviousness-type double patenting over claims 1-11 of co-pending Application No. 11/253,322; over claims 21-61 of co-pending Application No. 10/766,403; and over claims 11, 14-27, 29-30, 34, and 36-37 of co-pending Application No. 11/070,768;

(d) claims 1-30 under 35 U.S.C. §102(e) as being anticipated by 6,403,567 and its PCT equivalent (WO 00/078779);

(e) claims 1-15, 17-24, and 30 under 35 U.S.C. §102(b) as being anticipated by Verani (U.S. Patent No. 6,026,317);

(f) claims 1-30 under 35 U.S.C. §102(a) and/or (b) as being anticipated by Gao et al.; and

(f) claims 1-30 under 35 U.S.C. §103(a) as being obvious over 6,403,567.

The Abstract was also objected to.

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REJECTION OF CLAIMS 1-15, 17-24, and 30 under 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 1-15, 17-24, and 30 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner has stated that

The definitions of active ingredients in claims 1-15, 17-24, and 30 are directed to a vast number of chemical compounds which have not been described in the instant disclosure in a manner permitting the ordinary practitioner to have the guidance necessary to make a very large proportion of the compounds encompassed.

The Examiner has further directed Applicant's attention to *In re Wands* [858 F.2d, 731,737; 8 USPQ 2d 1400, 1404 (Fed cir. 1988)].

Although not agreeing with the Examiner's rejection, in an effort to advance this application to allowance, Applicant has amended claims 1 and 17, which are believed to render the issues raised by the Examiner moot. Applicant reserves the right to file continuing applications directed toward the canceled matter.

REJECTION OF CLAIMS 5 and 25 under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 5 and 25 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has requested that the Applicant define the term "iv bolus" at its first occurrence in an independent or a dependent claim following an independent claim.

Although not agreeing with the Examiner's rejection, in an effort to advance this application to allowance, Applicant has amended claims 6-9 and 25-26 to recite "intravenous bolus". The cancellation of claim 5 makes the Examiner's rejection of claim 5 moot.

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**PROVISIONAL REJECTION OF CLAIMS 1-30 FOR NON-STATUTORY DOUBLE
PATENTING**

The Examiner has provisionally rejected claims 1-30 for non-statutory double patenting over claims 1-11 of co-pending Application No. 11/253,322; over claims 21-61 of co-pending Application No. 10/766,403; and over claims 11, 14-27, 29-30, 34, and 36-37 of co-pending Application No. 11/070,768.

REJECTION OF CLAIMS 1-30 under 35 U.S.C. §102 (e)

The Examiner has rejected claims 1-30 under 35 U.S.C. §102(e) as being anticipated by 6,403,567 and its PCT equivalent (WO 00/078779). The Examiner stated that:

Applicant is referred to claims 1, 8, 10, and 11-13 wherein the compound, also known as CVT-3164 [sic], is disclosed as part of a pharmaceutical composition and as having utility in the imaging of mammalian cardiac circulatory systems. See also CV Therapeutics '770 (PTO-1449 ref. B2) which is the PCT equivalent to the '567 reference and also anticipates the instant noted claims for the same reasons.

The Applicant respectfully draws the Examiner's attention to the quotation from 35 U.S.C. §102 provided in the subject Office Action. The definition for anticipation under 102 stated that "the invention" was described in an application or patent. To be anticipated, all of the subject matter of a claim must be clearly set forth in a single reference. Applicant draws the Examiner's attention to independent claims 1 and 17 of the subject application as amended above. In amended claims 1 and 17 of the subject application specific N-pyrazole and C-pyrazole adenosine molecules are set forth. In amended claim 1 an amount and method for administration of the specific compounds is set forth. In amended claim 17 of the subject application specific N-pyrazole and C-pyrazole adenosine molecules are set forth. Also, in amended claim 17 there is a recitation that the administration "causes at least a 2.5 fold increase in coronary blood flow that is achieved within about 1 minute from the administration of the A_{2A} receptor agonist". Neither the '567 reference, nor its PCT equivalent, discusses C-pyrazole substituted adenosine compounds. In addition, neither the '567 reference, nor its PCT equivalent" discusses administration by intravenous bolus or provides information on the increase in coronary blood flow. Applicant also respectfully points out that claims 2-16 and 17-30 of the present application are dependent claims carrying the limitations of the independent

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claim from which they depend. For these reasons Applicant requests that the Examiner reconsider the rejection of claims 1-30 under 35 U.S.C. §102(e) as being anticipated by 6,403,567 and/or its PCT equivalent (WO 00/078779).

REJECTION OF CLAIMS 1-15, 17-24 and 30 under 35 U.S.C. §102 (b)

The Examiner has rejected claims 1-15, 17-24, and 30 under 35 U.S.C. §102(b) as being anticipated by Verani '317 (PTO-1449 ref. A11). The Examiner has pointed out column 2, lines 54-67 and the continuation into column 3, column 3, lines 43-67, the Examples at columns 5-10, and claims 1-3 and 15-23.

Applicant respectfully points out that '317 is directed to compound CGS-21680 and that the amended claims of the subject application do not include compound CGS-21680. For this reason, Applicant requests the Examiner to reconsider the rejection of claims 1-15, 17-24, and 30 under 35 U.S.C. §102(b) as being anticipated by Verani '317 (PTO-1449 ref. A11).

REJECTION OF CLAIMS 1-30 under 35 U.S.C. §102 (a) and/or (b)

The Examiner has rejected claims 1-30 under 35 U.S.C. §102 (a) and/or (b) as being anticipated by Gao et al. (PTO-1449 ref. C2). The Examiner has pointed out the abstract "wherein both CVT-3033 and CVT-3164[sic] are disclosed as having the desirable properties of inducing short term coronary vasodilation during myocardial imaging in the presence of radionuclides."

Applicant respectfully directs the Examiner's attention to the above amended claims. Gao et al. does not provide "a method of producing coronary vasodilation without significant peripheral vasodilation comprising administering by intravenous (iv) bolus at least 10 µg of at least one A_{2A} receptor agonist" (as taught in amended claim 1 of the subject application.) Nor does Gao et al. provide "a method of myocardial perfusion imaging --- wherein the administration of the A_{2A} receptor causes at least a 2.5 fold increase in coronary blood flow that is achieved within about 1 minute from the administration of the A_{2A} receptor agonist" (as taught in amended claim 17 of the subject application.) Applicant respectfully points out that claims 1 and 17 are the only independent claims in the subject application; the rest of the claims depending directly or indirectly from these two claims. For these reasons Applicant requests that the Examiner reconsider the rejection of claims 1-30 under 35 U.S.C. §102 (a) and/or (b).

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REJECTION OF CLAIMS 1-30 under 35 U.S.C. §103 (a)

The Examiner has rejected claims 1-30 under 35 U.S.C. §103 (a) as being unpatentable over Zablocki et al. '567 (PTO-1449 ref. AB1). The Examiner stated that:

Zablocki et al. '567 (PTO-1449 ref. AB1) discloses in claims 1, 8, 10, and 11-13 and in associated textual explanations that the compound, also known as CVT-3164 [sic], is part of a pharmaceutical composition and as having utility in the imaging of mammalian cardiac circulatory systems.

Zablocki et al. '567 does not expressly disclose all of the specific details of the administration of pharmaceutical compositions containing CVT-3164 [sic] found in the instant claims.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to conduct routine experimentation to determine the optimal conditions of administration of a CVT-3164 [sic]-containing compositions to produce the best possible radionuclide-based cardiac circulatory imaging.

Therefore, the instant claimed method of inducing selective myocardial vasodilation for the purpose of enhancing the imaging of cardiac circulation would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant respectfully draws the Examiner's attention to the fact that for a document to render the subject claims obvious, there must have been some motivation to go from that document to the present claims and that the step from the document to the present claims must have been taken without undue experimentation.

As the Examiner is aware, to establish *prima facie* obviousness, two basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable likelihood of success in light of the prior art. *Brown & Williamson Tobacco Corp. v. Phillip Morris Inc.* 229 F.3d 1120, 56 USPQ2d 1456, 1459 (2000) citing *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicant respectfully draws the Examiner's attention to '567. This patent provides general discussion as to the pharmaceutical composition for the compounds taught; provides a laundry list of methods for administration of the active compound; and provides no discussion

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regarding the length of time for dose administration, the increase in coronary blood flow that is achieved or the time in which that increased flow is achieved.

Thus, '567 provides no motivation to move from it to the present invention. There is nothing in '567 to point a person skilled in the art directly, without undue experimentation, to a specific pharmaceutical composition, or an intravenous administration, to a rapid bolus delivery of that intravenous administration, or to an increase in coronary blood flow.

Applicant also draws the Examiner's attention to the enclosed (as Appendix C) copy of the Adenoscan® prescribing information. On page 8 of the prescribing information (under DOSAGE AND ADMINISTRATION) it is stated that the Adenoscan product is for continuous peripheral intravenous infusion with the recommended dose for adults being infused for six (6) minutes.

Applicants respectfully point out that given the general information in '567 and the specific information about a commercial product for myocardial perfusion imaging (Adenoscan) a person skilled in the art would not be led from the general information in '567 to the specific dose and administration details of the subject application without undue experimentation. Applicant believes that there is no motivation to move from either '567, or a combination of '567 and the Adenoscan prescribing information, to the subject invention.

For the above reasons, Applicant requests that the Examiner reconsider his rejection of claims 1-30 under 35 U.S.C. §103 (a) as being unpatentable over Zablocki et al. '567 (PTO-1449 ref. AB1).

THE ABSTRACT OBJECTION

The Examiner objected to the abstract as being "too brief because it fails to identify the particular active ingredient(s) required to carry out the instant claimed process."

Enclosed with this Response is a marked up Abstract. A clean copy of the amended Abstract is attached as Appendix A. Applicants believe that the amended Abstract overcomes the Examiner's rejection, and ask the Examiner to approved the amended Abstract.

GENERAL COMMENTS

The following claim amendments have been made:

Claim 1: The chemical name and structure have been added for CVT-3146 and CVT-3033. Support for the chemical name and structure for CVT-3146 can be found on page 18,

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starting on line 16. Support for the structure for CVT-3033 can be found on page 19, line 3. Support for the chemical name for CVT-3033 can be found on page 17, lines 20 and 21. Support for "significant" can be found on page 9, lines 17-18 and page 38, lines 23-24. Support for "intravenous (iv) bolus" can be found in claim 5.

Claim 13: The typographical error at the end of claim 13 has been corrected so that the amount is "600 µg". Support for this can be found in claim 1, as well as claims 12, 14, and 15.

Claim 17: The chemical name and structure have been added for CVT-3146 and CVT-3033. Support for the chemical name and structure for CVT-3146 can be found on page 18, starting on line 16. Support for the structure for CVT-3033 can be found on page 19, line 3. Support for the chemical name for CVT-3033 can be found on page 17, lines 20 and 21. A typographical error in line 2 of claim 17 has been corrected to show "an" instead of "a".

DRAWINGS

The Examiner has indicated that informal drawings, which are acceptable for examination purposes only, have been submitted. Applicant will be happy to provide formal drawings when the application is allowed.

Conclusion

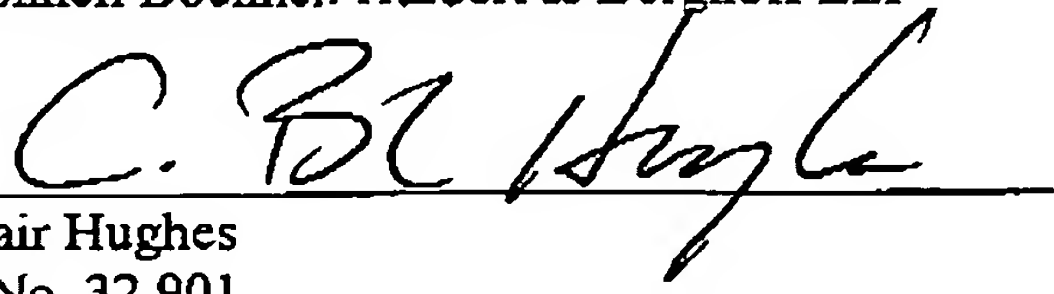
Applicants wish to point out that the cancellation of any subject matter in the claims pending as of this Office Action has been made without prejudice and without response to any arguments posed by the Examiner. Applicants reserve the right to prosecute any canceled subject matter in continuing applications.

Applicants submit that the claims are in condition for allowance. A Notice of Allowance is requested, and a prompt mailing thereof would be much appreciated. Should the Examiner have any questions, he is invited to contact the undersigned attorney at (312) 913-2123.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: August 29, 2006

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APPENDIX A

Clean Copy of Abstract as amended herein